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09/848,948	05/04/2001	Samir M. Hanash	A31909-PCT USA	8499

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BAKER & BOTTS, L.L.P.  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/848,948	<b>Applicant(s)</b> HANASH ET AL.	
	<b>Examiner</b> Stephen L. Rawlings, Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 6-13 and 19-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>20031008</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The amendment filed October 8, 2003 is acknowledged and has been entered. Claims 1 and 4 have been amended.
2. Claims 1-32 are pending in the application. Claims 6-13 and 19-32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention or species of invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7 filed .
3. Claims 1-5 and 14-18 are currently subject to examination.

#### ***Grounds of Objection and Rejection Withdrawn***

4. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action mailed April 9, 2003 have been withdrawn.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:  

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 14 is drawn to a kit comprising a component for detecting the presence of S100-A7, S100-A8, or S100-A9. The claim encompasses a genus of kits comprising a

genus of components. The genus of components includes components that bind S100-A7, S100-A8, or S100-A9, such that the resulting complex is detectable.

The specification describes an antibody for detecting the presence of S100-A7, S100-A8, or S100-A9. However, the specification does not describe any other component for detecting the presence of S100-A7, S100-A8, or S100-A9, which component binds S100-A7, S100-A8, or S100-A9 in a detectable manner.

Given the written description, the skilled artisan can envision an antibody that will bind S100-A7, S100-A8, or S100-A9, such that the resulting complex can be detected. However, even given benefit of the disclosure, the skilled artisan could not envision or recognize any other type of component encompassed by the genus, which might bind S100-A7, S100-A8, or S100-A9, such that the resulting complex is detectable. Absent a written description that would allow the skilled artisan to immediately envision or recognize at least a substantial number of members of the genus of components of which the claimed kits are comprised, the disclosure would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

MPEP § 2163.02 states, “[a]n objective standard for determining compliance with the written description requirement is, ‘does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed’ ”. The courts have decided:

The purpose of the “written description” requirement is broader than to merely explain how to “make and use”; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Furthermore, in deciding *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the Court held that a generic statement that defines a genus of nucleic acids, or by analogy, and more aptly in this instance, a genus of components *by only their functional activity* does not provide an adequate written description of the genus. Furthermore, the Court indicated that while applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a precise definition of a representative number of members of the genus, such as by reciting the structure, formula, chemical name, or physical properties of those members, rather than by merely reciting a wish for, or even a plan for obtaining a genus of molecules having a particular functional property. The recitation of a functional property alone, which must be shared by the members of the genus, is merely descriptive of what the members of genus must be capable of doing, not of the substance and structure of the members. Thus, having merely described the members of the genus of components as somehow suitable for use in detecting S100-A7, S100-A8, or S100-A9, or even perhaps as capable of detectably binding S100-A7, S100-A8, or S100-A9, does not describe the genus in a manner sufficient to meet the written description requirements.

*The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement* (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has

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Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 4, 5, 14, and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/35985 A1.

WO 98/35985 A1 teaches an analysis of the proteins in various types of lung tumors revealed the presence of MRP8/S100-A8 and MRP14/S100-A9, whereas an analysis of the patient's normal lung tissue indicated the absence of these proteins. WO 98/35985 A1 teaches an antibody, which binds an epitope formed by heterodimerization of MRP8/S100-A8 and MRP14/S100-A9, which is commercially available as a pre-packaged kit (page 20, lines 5-8). WO 98/35985 A1 teaches the antibody also binds MRP14/S100-A9 (page 20, line 5-7). MRP14/S100-A9 teaches the antibody can be used to determine and compare the amounts of MRP14/S100-A9 in the serum of a subject having a lung tumor and the serum of an unaffected subject (page 20, lines 16-25). WO 98/35985 A1 teaches the determination was made by integrated analysis of reactivity in a visualized band (page 20, lines 22-25), thereby implicitly teaching that either the antibody that binds MRP14/S100-A9 is detectably labeled or a detectably labeled secondary antibody, which binds the primary antibody, is used in

determining the amount of MRP14/S100-A9 in the serum samples. WO 98/35985 A1 expressly teaches the disclosed antibody can be radioactively labeled (page 17, line 21). WO 98/35985 A1 teaches the disclosed findings indicate a role for antibodies against MRP in screening for different types of cancer that express the MRPs (page 20, lines 26 and 27). Accordingly, WO 98/35985 A1 teaches a method for detecting a lung tumor is an animal comprising separating proteins in a serum sample from an animal, transferring the proteins to a membrane, probing the proteins with an antibody specific for an epitope formed by heterodimerization of MRP8/S100-A8 and MRP14/S100-A9, and quantifying the amount of protein bound by the antibody as an indication of the presence of a lung tumor (page 20). WO 98/35985 A1 also teaches a method for detecting a lung tumor comprising treating a tissue section with an antibody specific for an epitope formed by heterodimerization of MRP8/S100-A8 and MRP14/S100-A9 and determining the amount of antibody bound as an indication of the presence of a lung tumor (page 20).

9. Claims 14 is rejected under 35 U.S.C. 102(b) as being anticipated by BIO-RAD Life Sciences Research Products Price List Q (March 1991).

BIO-RAD Life Sciences Research Products Price List Q (March 1991) teaches a kit comprising a component for detecting the presence of S100-A7, S100-A8, or S100-A9 in a biological sample. For example, the reference teaches "Immuno-Blot Assay Kits", which comprise at least one component for detecting the presence of S100-A7, S100-A8, or S100-A9 in a biological sample (page 236).

10. Claims 14 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Newton et al. (*J. Immunol.* **160**: 1427-1435, 1998).

Newton et al. teaches a commercially available, pre-packaged kit comprising a component for detecting MRP8/S100-A8 and MRP14/S100-A9, which component is an anti-S100 antibody (page 1428, column 1).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 3 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/35985 A1, as applied to the rejection of claims 1, 2, 4, 5, 14, and 15 set forth *supra*, in view of BIO-RAD Life Sciences Research Products Price List Q (March 1991), pages 190 and 233-240.

WO 98/35985 A1 teaches that which is set forth above, but does not expressly teach the method of claim 3 wherein the immunoassay is an immunoprecipitation assay. In addition, WO 98/35985 A1 does not teach a kit comprising a detectably labeled anti-S100 antibody (claim 16), wherein the label is a radioactive, fluorescent, colorimetric, or enzyme label (claim 17), or a kit comprising an anti-S100 antibody and a labeled secondary antibody that binds the anti-S100 antibody (claim 18).

BIO-RAD Life Sciences Research Products Price List Q (March 1991) teaches a kit comprising a component for detecting the presence of S100-A8 and/or S100-A9 in a biological sample, as set forth *supra*. In addition, the reference discloses the application of immunobead reagents for immunoprecipitation (page 190). The reference teaches immunoprecipitation can be used to detect and/or quantify any protein to which a given antibody binds (page 190). The reference teaches the antibody used to immunoprecipitate the protein to which the antibody binds can be radioactively or fluorescently labeled, or can comprise an enzyme label, such that the antibody is detectable in a colorimetric assay (page 190). Alternatively, or in addition, the reference discloses the application of immunoblot, i.e., Western blot, assay kits comprising a labeled secondary antibody that binds to a primary antibody for use in detecting and/or quantifying the protein to which the primary antibody binds; see, e.g., pages 233-240.

Therefore, BIO-RAD Life Sciences Research Products Price List Q (March 1991) shows it was routine and conventional at the time of invention to detect and quantify a protein by immunoprecipitation and/or immunoblot using a primary antibody that is detectably labeled, e.g., fluorescently or radioactively labeled, or conjugated to an enzyme, such that it is detectable by a colorimetric assay, or alternatively, using a unlabeled primary antibody and a detectably labeled secondary antibody that binds the primary antibody. BIO-RAD Life Sciences Research Products Price List Q (March 1991) shows it was routine and conventional at the time of invention to manufacture and use kits comprising reagents used in the same process.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to practice the method of claim 2, wherein the immunoassay is an immunoprecipitation assay for the following reasons: WO 98/35985 A1 teaches an antibody that binds MRP14/S100-A9 can be used in an immunassay to detect and/or quantify MRP14/S100-A9 and as taught by BIO-RAD Life Sciences Research Products Price List Q (March 1991), it was routine and conventional at the time of the invention to detect and/or quantify a protein by immunoprecipitation. In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to manufacture a kit comprising reagents for detecting S100-A8 and/or S100-A9 and to use it for the diagnosis of a lung tumor, which kit comprises the detectably labeled antibody disclosed by WO 98/35985 A1 for the following reasons: WO 98/35985 A1 teaches the antibody can be used to screen for lung cancer and as taught by BIO-RAD Life Sciences Research Products Price List Q (March 1991), it was routine and conventional to detectably label the antibody used to immunoprecipitate a protein to which the antibody binds in the process of detecting and/or quantifying the protein by immunoprecipitation and other immunoassays; and as further taught by BIO-RAD Life Sciences Research Products Price List Q (March 1991), it was routine and conventional at the time of invention to manufacture and use kits comprising reagents used in the same process. Alternatively, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to manufacture a kit comprising reagents for the diagnosis of a lung tumor, which kit comprises the antibody disclosed by WO 98/35985

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A1, and which kit further comprises a detectably labeled secondary antibody that binds the antibody disclosed by WO 98/35985 A for the following reasons: again, WO 98/35985 A1 teaches the antibody can be used to screen for lung cancer; and as taught by BIO-RAD Life Sciences Research Products Price List Q (March 1991), it was routine and convention to use a labeled secondary antibody that binds the antibody used to immunoprecipitate a protein in the process of detecting and/or quantifying the protein by a process comprising immunoprecipitation and other immunoassays, e.g., Western blot analysis; and again, as further taught by BIO-RAD Life Sciences Research Products Price List Q (March 1991), it was routine and conventional at the time of invention to manufacture and use kits comprising reagents used in the same process. One of ordinary skill in the art at the time of invention would have been motivated to do so, because kits provide ease and convenience and WO 98/35985 A1 teaches detecting and/or quantifying MRP14/S100-A9 in the serum of a subject provides an indication of the presence of a lung tumor in the subject.

### ***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1, 2, 4, and 5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/461,424. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Claim 1, 2, 4, and 5 of the instant application are drawn to a method for diagnosis of a lung tumor comprising detecting the presence of S100-A7, S100-A8, and/or S100-A9 in the serum of a subject by an immunoassay; whereas claims 13-15 of the copending application are drawn to a method for detecting a lung tumor in an animal comprising detecting the presence of S100-A9 (MRP14) in a tissue sample or the serum of a subject by an immunoassay.

Although claim 1 of the instant application recites a step of comparing the levels of the protein in the subject's serum and a control, and claims 13-15 of the copending application do not, it would have been obvious to one ordinarily skilled in the art at the time of invention to include such a step in practicing the methods of claims 13-15 of the copending application. It was routine and conventional at the time of the invention to include in such an assay a sample to establish a background or basal level, i.e., a negative control. Nonetheless, claim 13 of the copending application recites a "correlating" step; therefore, it would have been obvious to one ordinarily skilled in the art to correlate the amount of the protein and the presence of a lung tumor by comparing the levels of the protein in the subject's serum and appropriate positive and negative controls to determine the amount of the protein that is indicative of the presence of lung cancer in the subject.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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15. Claims 3 and 14-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/461,424, as applied to claims 1, 2, 4, and 5 in the obviousness-type double patenting rejection above, and further in view of BIO-RAD Life Sciences Research Products Price List Q (March 1991), pages 190 and 233-240. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

BIO-RAD Life Sciences Research Products Price List Q (March 1991) discloses that which is set forth above. Therefore, although instant claim 3 recites a method comprising an immunoprecipitation assay, whereas claims 13-15 of the copending application do not, as taught by BIO-RAD Life Sciences Research Products Price List Q (March 1991), it was routine and conventional at the time of invention to detect and quantify a protein by immunoprecipitation and/or immunoblot.

Instant claims 14-18 are drawn to a kit for diagnosing a lung tumor. Although claims 13-15 of the copending application are not directed to a kit for diagnosing a lung tumor, the claims are directed to a method for diagnosing a lung tumor. The disclosure of the methods of claims 13-15 of the copending application would have rendered a kit for practicing the disclosed methods obvious to one ordinarily skilled in the art at the time of invention, because, as taught by BIO-RAD Life Sciences Research Products Price List Q (March 1991), it was routine and conventional at the time of invention to manufacture and use kits comprising reagents used in the same process. In addition, as further as taught by BIO-RAD Life Sciences Research Products Price List Q (March 1991), it was routine and conventional at the time of invention to detect and/or quantify a protein by an immunoassay, e.g., immunoprecipitation and/or immunoblot, using a primary antibody that is detectably labeled, e.g., fluorescently or radioactively labeled, or conjugated to an enzyme, such that it is detectable by a colorimetric assay, or alternatively, using a unlabeled primary antibody and a detectably labeled secondary antibody that binds the primary antibody. Accordingly, the disclosure of the methods of claims 13-15 by the copending application would have rendered the kit of claims 14-18

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of the instant application obvious to one ordinarily skilled in the art at the time of invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

16. No claims are allowed.


17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1642

slr  
April 20, 2004

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600